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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : G. Nickol
Group Art Unit : 1642
Applicants : Ugo Ripamonti, et al.
Application No. : 09/540,466
Confirmation No. : 2489
Filed : March 31, 2000
For : METHODS FOR INDUCING ANGIOGENESIS
USING MORPHOGENIC PROTEINS AND
STIMULATORY FACTORS

New York, New York
May 10, 2001

Hon. Commissioner
for Patents
Washington, D.C. 20231

REPLY TO RESTRICTION REQUIREMENT

Sir:

This is in reply to the April 10, 2001 Restriction Requirement in the above-identified application. Applicants are filing this reply before the expiration of the shortened statutory period for this reply -- May 10, 2001 -- and thus no extension fee is due.

The Examiner has required restriction of the claims of this application under 35 U.S.C. § 121 into one of the following two Groups:

Group I: Claims 1, 5-12 drawn to a method of inducing angiogenesis comprising administering an effective amount of a morphogenic protein

Group II: Claims 2-20 drawn to a method of improving the angiogenic inductive activity of a monomeric morphogenic protein by co-administering a protein stimulatory factor to a vascular tissue defect.

The Examiner contends that inventions I and II have acquired separate status in the art because inventions I and II are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules sued, response variables, and criteria for success. Accordingly, restriction to one of the two inventions is required. Applicants traverse.

Applicants request that the claims of Groups I and II be examined together. The Manual of Patent Examining Procedure (MPEP) states that there are two criteria for a proper requirement of restriction between patentably distinct inventions. The first is that the inventions must be independent or distinct as claimed. The second is that there must be a serious burden on the Examiner if restriction is not required. The MPEP further states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions". MPEP § 803.

Whether the Examiner is correct in his "distinctness" contention is irrelevant. Here, there is no serious burden for the Examiner to search the claims of both Groups I and II because these searches overlap extensively, such that a search for the method of inducing agiogenesis using the morphgenic protein of Group I would reveal any art relating to the method of inducing agiogenesis using a

morphogenic protein and morphogenic protein stimulatory factor of Group II. For these reasons, applicants request that Group I and II be rejoined.

Applicants request that the Examiner examine rejoined Groups I and II. If the Examiner does not agree with applicants' proposal to rejoin Groups I and II, applicants provisionally elect with traverse the claims of Group II for initial substantive examination. 37 C.F.R. § 1.143. This election is made expressly without waiver of applicants' rights to continue to prosecute and to obtain claims to the non-elected and/or canceled subject matter either in this application or in other applications claiming priority herefrom.

The Examiner has also stated that Group II is generic to a plurality of disclosed patentably distinct species comprising the following morphogenic proteins:

- a) osteogenic protein (claim 5)
- b) BMP's, COP's, etc. (claim 6)
- c) OP-1, BMP's, GDF's, etc. (claim 8 - as drawn to monomeric species)
- d) OP-1, BMP's, GDF's, etc. (claim 10 - as drawn to dimeric species)
- e) OP-1 (claim 11)

The Examiner contends that the above species represent separate and distinct molecules with different structures and functions. The Examiner asserts that each species would require different searches and the consideration of different patentability issues. Applicants traverse.

Applicants elect the species, OP-1, with traverse, for further prosecution in this application. Applicants make this species election expressly without waiver of their right

to file for and obtain claims directed to the non-elected subject matter in divisional or continuing applications claiming priority and benefit herefrom, or from a related application, under 35 U.S.C. § 120.

The Examiner has further stated that Group II is generic to a plurality of disclosed patentably distinct species comprising the following protein stimulatory factors:

- a) aFGF, bFGF, TGF- β , etc. (claim 13)
- b) bFGF or TGF- β 1 (claim 14)
- c) bFGF (claim 15)
- d) TGF- β 1 (claim 16)

The Examiner contends that the products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. The Examiner states that each species would require different searches and the consideration of different patentability issues.

Applicant elects the species bFGF, with traverse, for further prosecution. Applicants make this species election expressly without waiver of their right to file for and obtain claims directed to the non-elected subject matter in divisional or continuing applications claiming priority and benefit herefrom, or from a related application, under 35 U.S.C. § 120.

The Examiner has further stated that Group II is generic to a plurality of disclosed patentably distinct species comprising the following modes of administration:

- a) morphogenic protein and stimulatory factor are administered simultaneously (claim 17)
- b) morphogenic protein and stimulatory factor are administered separately (claim 1).

The Examiner contends that the steps of the above species are completely distinct and impart different biological functions and uses such that one species could not be interchanged with the other. The Examiner asserts that each species would require different searches and the consideration of different patentability issues.

Applicants elect the species of simultaneous administration, with traverse, for further prosecution in this application. Applicants make this election of this species expressly without waiver of their right to file for and obtain claims directed to the non-elected subject matter in divisional or continuing applications claiming priority and benefit herefrom, or from a related application, under 35 U.S.C. § 120.

CONCLUSION

In view of the above, applicants request that the Examiner examine the pending claims in this application. Applicants request favorable consideration and early allowance of the pending claims.

Respectfully submitted,

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